## REMARKS

Claims 1, 26-29, and 53 are pending in the present application.

Claims 2-25 and 30-52 have been cancelled without prejudice.

Claims 1, 26, 28, and 53 have been amended.

Claim 1 has been amended to replace the phrase"cancer-associated Inhibitor of Apoptosis-family protein (IAP-family protein)" with the phrase "survivin protein" and to replace the phrase "immunoreactive gene product" with "cytokine". Support for these amendments can be found in the specification, e.g., at page 8, lines 13-25; page 17, lines 5-11; and in examples 1-8 on pages 31-37, and examples 14-19 on pages 40-47.

Claim 26 has been amended to specify that the DNA construct encoding the survivin protein comprises elected SEQ ID NO: 3, and to delete the other sequences from the claim.

Claim 28 has been amended to specify that the DNA construct encoding the immunoreactive cytokine comprises elected SEQ ID NO: 7, and to delete the other sequences from the claim.

Claim 53 has been amended in accordance with the changes made in claim 1, in order to provide proper antecedent basis.

No new matter is introduced by these amendments.

**Claim Objections.**

Claims 26 and 28 were objected to for referring to non-elected sequence numbers. In response, claims 26 and 28 have been amended to only refer to the elected sequence numbers (i.e., SEQ ID NO: 3 and SEQ ID NO: 7, respectively).

**Rejections Under the First Paragraph of 35 U.S.C. §112.**

Claims 1, 26-29, and 53 stand rejected under the first paragraph of 35 U.S.C. §112, as allegedly failing to comply with the written description requirement. According to the Office Action, the terms "cancer-associated IAP-family protein" and "immunoreactive gene product" are so broadly defined that the specification would not have reasonably conveyed to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time the application was filed. While Applicants do not agree with this assertion, the claims have been amended to substitute the term "survivin protein" for the term "cancer-associated IAP-family protein " and to substitute the term "cytokine" for the term "immunoreactive gene product". These changes are well supported and described in the specification.

In particular, the specification, at page 8, lines 13-25 and page 17, lines 5-11, specifically describes a DNA construct encoding a survivin protein and a cytokine as a preferred embodiment of the invention. Various forms of survivin are well known in the art, e.g., as indicated in the specification at page 15, lines 9-30. Cytokines are also well known, and are described in the specification at page 17, lines 5-31. The working examples, particularly examples 1-8 on pages 31-37, and examples 14-19 on pages 40-47 provide *in vivo* and *in vitro* data from vaccinated mice demonstrating the utility of the present compositions to elicit an immune response against tumor cells, as well. Accordingly, there is ample description in the application, including working examples, to convey to one of ordinary skill in the art that the inventors had possession of the presently claimed invention at the time the application was filed. Withdrawal of this rejection is warranted.

**Rejections Under 35 U.S.C. §102.**

Claims 1 and 26 stand rejected as allegedly being anticipated under 35 U.S.C. §102(b) by Bennett *et al.* (US 6,335,194). According to the Office Action, Bennett *et al.*

teach antisense modulation of survivin expression, and an expression vector for survivin that allegedly reads on claims 1 and 26, because the expression vector encodes non-native gene products, such as *lacZ*, which would be immunoreactive. These arguments are inapposite to the present claims, which are specifically directed to a DNA construct encoding a survivin protein and a cytokine. Bennett *et al.* does not teach or suggest such a DNA construct. Withdrawal of this rejection is warranted.

Claims 1 and 53 stand rejected as allegedly being anticipated under 35 U.S.C. §102(e) by Girard *et al.* (US 2004/0224408). According to the Office Action, Girard *et al.* teach genes and proteins of the THAP family and their use in the treatment of disease and as chemokine binding agents. According to the reference, THAP1 may contribute to pro-apoptotic activity by down-regulating survivin. Girard *et al.* refers to nucleotide and protein sequences for survivin and for the chemokine CCL21. The Office Action also indicates that the reference teaches that some chemokines act on immune system cells, and that some embodiments of the alleged invention disclosed therein "relate to a device for delivering the THAP-type chemokine binding agent to the subject. The reference also teaches that THAP-family proteins or portions thereof can be used to modulate apoptosis (see paragraph [0022]) and that some THAP-family proteins or fragments thereof can bind to the chemokine CCL21 (see paragraph [0027-0031]). The arguments in the Office Action do not seem to be focused on the present invention, however. Clearly, THAP-family proteins are different compounds from IAP-family proteins.

It is not clear from the Office Action how the various disjunct disclosures of Girard *et al.* are alleged to disclose the present invention. There is no teaching or suggestion in Girard *et al.* to prepare a DNA vaccine suitable for eliciting an immune response against cancer cells comprising a DNA construct encoding both an IAP-family protein and an immunoreactive gene product as originally claimed. Cited paragraph [1454], read in context with paragraphs [1453-1458] merely indicates that the survivin gene is regulated by THAP-

family proteins. This does not amount to a teaching or even a suggestion that a DNA construct encoding survivin and a cytokine can be used to stimulate an immune response against cancer cells. This reference simply does not teach or suggest a DNA construct encoding survivin and a cytokine, much less the use of such a material as a vaccine against cancer cells, as presently claimed. Mere isolated references to survivin and chemokines such as CCL21 in the same document do not equate to an anticipation of the presently claimed invention under 35 U.S.C. §102(e) or even to obviousness under 35 U.S.C. §103(a). Accordingly, this rejection should be withdrawn, as well.

**Rejections Under 35 U.S.C. §103(a).**

Claims 1, 26, and 27 stand rejected as allegedly being obvious under 35 U.S.C. §103(e) over the combination of Bennett *et al.* taken with Pawelek *et al.* (US 6,190,657), while claims 1 and 28 stand rejected as allegedly being obvious under 35 U.S.C. §103(e) over the combination of Girard *et al.* taken with Tanabe *et al.* Neither of these rejection is warranted.

Bennett *et al.* and Girard *et al.* are described above. Pawelek *et al.* merely disclose the use of certain *S. typhimurium* bacteria as vectors for gene delivery, and do not cure the defects of Bennett *et al.* The combination of Bennett *et al.* and Pawelek *et al.* simply does not teach or suggest a DNA construct that operably encodes both a survivin protein and a cytokine as a DNA vaccine against cancer cells. Thus, the present claims are patentable over the combination of Bennett *et al.* taken with Pawelek *et al.*

Similarly, Tanabe *et al.* merely disclose the sequence of murine CCL21 (SEQ ID NO: 7). The combination of Girard *et al.* with Tanabe *et al.* would not have rendered claimed DNA vaccine obvious to one or ordinary skill in the art, however, since there is no teaching or suggestion in the combined references to construct a DNA vaccine encoding both a survivin protein (e.g., SEQ ID NO: 3) and a cytokine (e.g., SEQ ID NO: 7). In addition,

these references would not have provided the necessary reasonable expectation of success, since Girard *et al.* focus on THAP-family proteins, not survivin, and merely mention that survivin expression is regulated by the THAP-family proteins. Girard *et al.* teach nothing about eliciting an immune response against tumor cells using a DNA that encodes a survivin protein and a cytokine. Accordingly, withdrawal of this rejection is warranted.

**Conclusion.**

In view of the foregoing amendments and traverse, Applicants request allowance of the present claims and early passage of the application to issue.

Respectfully submitted,

March 19, 2007

By _____
Talivaldis Cepuritis (Reg. No. 20,818)

OLSON & HIERL, LTD.
20 North Wacker Drive
36th Floor
Chicago, Illinois 60606
(312) 580-1180